



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

Member Discussion

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DR. GUTMANN: Welcome back everybody. We have until 11:45, right? Great. So, we'll take an hour and then wrap up.

Let me just go back because the language of risk was used so ubiquitously here that I skipped over too quickly something that is research risk to children, which is very important and we have really good language on that, but Dan had yesterday suggested a very helpful way of guiding and understanding that, where it is going to be part of our recommendation, that a 407 panel ought to determine where along the risk spectrum on research risk to children the protocol is and I'll turn it over to Dan to say how he thought we could be helpful without falling into the trap of trying to quantify or become so specific that it really is meaningless because you can't be overly specific here. So Dan.

DR. SULMASY: Just--(sneeze)

DR. GUTMANN: Bless you.

DR. SULMASY: In my discussions with Alan Fleischman yesterday about what it means to be one more thumb length over in the risk category, when I pressed him, I think he was very helpful in sort of giving stipulations of the kinds of things we might be talking about when we're talking about a minor increase over a minor increase over minimal risk, which is far too vague. And so I just think we ought to stipulate some things, as he suggested, such as pain, swelling, redness, missing school, and there are questions on how far you want to go, skin biopsy, EEG, and then what things might be off the table, you know, brain biopsy, liver biopsy, things like that that could sort of help us I think to be of concrete assistance to a 407 committee without--and making sure that we say we are not exhaustive and these are not the only examples and they've got to also be weighed against the vital importance issue, etc., but these are the kinds of things that we would generally think would fit into one category or another and we could talk about what fits in one bucket or the other, but to give some guidance I think would be helpful.

DR. ALLEN: I am a little bit confused because you just named a lot of procedures. Those strike me as burdens as opposed to risks. Burdens have risk, so could you clarify how that list is going to help us with the question of the research risk?

DR. SULMASY: They are both. I mean some of it are the harms of what could happen after those kinds of things, so the procedure itself, you know, the procedures become more risky. So lumbar puncture is a procedure, but it has many more risks than taking somebody's blood pressure, so they were sort of helpful entrees of the kinds of things we think would incur too much risk.

DR. GUTMANN: So I think there are two parts of our charge here that are important. One is to say based on kind of case law which is the case that has been approved, what has

counted as a minimal level above minimal risk? Give examples that are accessible examples of that and what is counted as higher than that, clear examples that would speak to answer Anita's question.

The other part, which I will say is not part of this framework, but I think outside of the framework in our report we should say is that a 407 committee should be constituted in a way that could determine as clearly as possible what the research risks are and state as clearly as possible what the level is because on both hearing and, in the case of yesterday, reading everything, there are many people who believe--many informed doctors who believe, as Dr. Alan Fleischman does--that the particular case that brought us to this charge is minimal level above minimal risk and not more than that, even though the report suggests it is more than that.

We are not going to determine that, but we ought to say that it is really important for a 407 panel to be able to say what that risk actually is, which again, is not--it's likelihood, but I'm talking about qualitative saying--so I thought Dan what you said and with the addition of what--and I see nods--we should recommend in the report outside of the framework itself. What you said is inside the framework, what I just said is just that, outside of that, that is just very important in order to know whether you satisfy a set of ethical principles -- to be able to tell the public and parents and children what the research risks, where they fall. John.

DR. ARRAS: Just a friendly amendment, and we might want to note that in some cases, even though the particular intervention is minor, that it might be repeated so many times during study that it could produce a bad effect.

The study that comes to mind for me is that growth hormone study that was approved under--I don't know how, but it was approved under 407, giving perfectly normal kids three placebo injections a week for two years. I mean that is a good example to me of a case where the negative effect is just over the top.

DR. GUTMANN: Yes, so we will state--we already do state duration reversibility, to me reversibility is extremely important when somebody doesn't stand to benefit from it. Christine.

DR. GRADY: I also think about adding a statement that says just because it is new intervention in children doesn't by definition make it greater than a minor increase over minimal risk. Because I think there is a tendency in the field to do that. If you do a study of a new intervention, new vaccine or a new drug, it's automatically assumed to be greater than a minor increase over minimal risk. And in this case, and in many cases, the adult data should be--and the animal data and all the scientific facts that about what we know about a particular intervention should be used to make a more nuanced decision about whether it is or isn't.

DR. GUTMANN: That could be of a part it.

At the same time, I would want that said in the same place that we said. But the medical community needs to tell us what the risks are and if they don't tell us what the risks are then the

newness of it is going to produce a rational fear factor. I think that's the responsibility that attaches to not vetoing newness, the responsibility of the medical community is to be as specific as possible about the risk and if it can't be specific at all then that is a problem.

Okay. And this is research risk, so we know we already have studies on adults, but and adults include 18 year olds.

Okay, now, we are on Transparency and Accountability. Sure.

DR. ATKINSON: I'd like to raise an issue about the compensation one. We've had discussions before about compensation versus tort, going the tort route, and I just wanted to be sure that everybody actually agreed with that one. We talked about it in working group B, but it never really was brought to everybody. I certainly think it is important and might even expand it to say "treatment" or "compensation," something along that line, but I wanted to be sure that everybody agreed that we should keep that in.

DR. GUTMANN: Everybody agree?

DR. WAGNER: Yes.

DR. FARAHANY: So I will chime in just because I was a big part of this debate last time. I think it is different in the case of children than in adults and that we should have it guaranteed. I do want to see this spelled out as specified as to exactly what we mean and what kind of, you know, we took earlier language out of this that was "systematized". I think some form of compensation for direct research related injuries is an essential component of any kind of research that happens in children.

DR. GUTMANN: That is a wholehearted agreement and some of us also think it should be with adults, but for this research to go forward in a case of some vital emergency, you want a plan, not a whole--it doesn't have to be a whole system, you don't want to wait, life is too short to wait for a whole system, a plan that says these children in the case of harm will be first of all treated and compensated.

Okay. Accountability Through Transparency. I'll read it.

Before proceeding with testing, the Secretary must provide clear communication of expected risks and expected benefits of the research. In addition, equally clear reasons must be publicly stated as to why government ethnically seek the informed consent of parents and the ascent of children without using them as means only--understanding that we're going to make that language broader, more capacious to different convergent views. There is a great deal of discussion during sessions, as well during round table, that engaging in communities early and often. Many members commented that community engagement needs to be expanded in the framework. So, this segues to community engagement and I wonder, Nelson, if you would you speak to that.

Maybe I should--should I read the next one too? Adequate provisions are made for soliciting the ascent of children in the permission of their parents or guardians. I guess that is a different one. No, let's hold on that.

So yeah, community engagement, Nelson.

DR. MICHAEL: I think we had some nice discussion yesterday about this too, but obviously for both pre and post-event, the idea of socializing this concept in the communities where this research is either planned to happen or could be expected to happen post-event is critical because you are talking about, I think, working obviously with susceptible children that, or also vulnerable research participants, there are going to be sectors of the community that historically have had reluctance to engage in research or have historical concerns with communications with the medical community at large. And therefore these kind of approaches have to be done from the beginning, from the very beginning planning stages with an active and continuous process of community engagement.

So this is really no different than a lot of discussions we had in moral science that stem from discussions of Guatemala, but there was, I think, a fairly broad uptake of the importance of doing this in this context.

DR. WAGNER: We need language for this bullet.

DR. GUTMANN: And so what I see as the suggestion here is when we talk about transparency and accountability, it ought to be broader than the language here, which is very specific, which is good, that the Secretary and the panel should give reasons, but also that accountability and transparency has to do with engaging the broader community in this process. Can we--Nelson, can I just call on you to give more specifics to what we want to put in there?

DR. MICHAEL: Um. Okay. I think that, again, I would borrow language from some of the guidelines that have already been published from UNAIDS and AVAC, take some of the language from good participatory practice guidelines, which fairly clearly states, and here again in terms that now are fairly specific as well, about the engagement of the community for the entire lifecycle of the research proposal. I think that would be important.

So in other words, this is not going to be a proposal that would be drawn up by research scientists and at the end of the day that protocol would then be presented, sort of at the last moment, to members of the community, but they would be engaged in the actual conception and the thought process, some of the deliberations of how the actual research protocol occurred and they should be a part of a research committee.

So that is the kind of language I would like to see in the report and it could be done I think in a fairly compact way.

DR. GUTMANN: Okay. Barbara and then Dan and Anita.

DR. ATKINSON: I'm wonder figure it shouldn't be a whole section, like number five. Really, it is not really transparency and accountability. To me it is important enough that it should be seen as a major part of the protocol, that we do start even before you do the protocol and you prove it to the 407 panel that you've actually got adequate community support before and after planning.

DR. GUTMANN: Okay. What I am struggling with is who the community is. I think, for example, one specific recommendation is the 407 panel should have members of, you know, the public--just as we have public representatives—we should have members of the public on it, which means from the beginning they would be involved, because the community is our whole society, right?

DR. MICHAEL: Right. I think some tangible examples of who that community could be would be the first responder community. I think that would be reasonable.

DR. GUTMANN: Although that, you know, I agree, but the first responder community is a community that has a very strong voice as seen by the fact that we have been getting--I was thinking that the community is more the general public that has much less insight and opportunity to get, I mean insight in the sense, the strict sense, of the word, it has a lot of insight and common sense, but it has less, it is less privileged to know what is going on and we don't hear from members of the general public--we hear from organized groups much more than we hear from members of the general public.

DR. MICHAEL: True.

DR. GUTMANN: So that is one of the things that I think we should --.

DR. WAGNER: What are the language needed -- I'm sorry.

DR. GUTMANN: Go on. Dan, sorry.

DR. SULMASY: Just to add to that, um, but you have been talking about the community engagement and the design and execution of the research, but part of what we heard yesterday was before you justify doing the research, you have to make sure there is enough community engagement and the result of the research, if successful, would be taken up by the community itself. So if we do this research and only 25% of the population is going to use let's say a vaccine, then in fact it has been a problem, um, um, and that we ought to be engaging them not only in the research itself, but in the actual widespread use, if it is under 407, for some sort of a public health emergency.

DR. GUTMANN: I have Anita and Alex.

DR. ALLEN: Dan said exactly what I was going to say that we need to make that nexus between the research and the public health benefit down the line. People need to be willing to take advantage of the research and if that doesn't happen then in some sense we failed.

DR. GUTMANN: Alex.

DR. GARZA: So, I don't disagree, but I think it's, I am trying to play this out in my mind practically how this would work, and so I agree that the community should be able voice whether they would find this beneficial or not, but that is very contextual, and what I mean by that is 40% of the American public, or even probably less than that, get a flu shot every year, I guarantee you when we have a pandemic with novel virus that rate will go up and so do people find it not very beneficial if it is just regular flu, but if it is something that is extraordinary, it is much more beneficial to them? And so presenting a question--

DR. GUTMANN: I think the answer is probably yes.

DR. GARZA: So presenting a question to them during a time of normalcy, saying do you find this of value, I think people would inherently say no. If you put it to them in a time of very complexity--

DR. GUTMANN: Alex, that is if you take a poll, but if you bring people into an actual deliberation and give them information and so, it is part of the point of educating people about what we are doing as a country to prepare.

DR. GARZA: Yeah.

DR. GUTMANN: I agree with you that how you do it practically is not easy, but to try to find ways of doing it, I think is going to be critical to the ability to move forward with the kind of research we're talking about. That's--so I think there is an ethical and practical component, although I understand that it is not going to be a poll.

DR. GARZA: Right, right. I just have some reservations about it, whether it would be a very difficult barrier to overcome.

DR. FARAHANY: But does it have to be a barrier? It could be, right, we are making a recommendation that we think it is an essential component, but not that if we--not if there is not

adequate community response or adequate community buy in that you don't proceed. Simply that an essential component of an ethical framework is to educate the public.

DR. GUTMANN: Right.

DR. GARZA: I am not advocating that we shouldn't get--

DR. GUTMANN: No, you're saying--

DR. FARAHANY: Don't let it be a bar.

DR. GARZA: Right.

DR. GUTMANN: Yeah. Nelson.

DR. MICHAEL: I am--detected the first fragment of sentence from your co-chair so let me give you an answer to the question he sort of asked, which was, um, so in the good participatory practice guidelines, they define stakeholders and they define community stakeholders, so let me give some granularity to this discussion and I think it will be helpful and it is only a few sentences.

So stakeholders would be trial participants, families of trial participants, perspective trial participants, individual residents within or surrounding the area where research is conducted, and then of this is specific HIV language so it is not that relevant.

DR. GUTMANN: So that's--see, that is what I was asking for. That is very helpful.

DR. MICHAEL: Then, treatment advocates and activists, NGOs, community-based organizations, community groups, religious leaders, opinion leaders, media government bodies and it goes on, but let me just--this is why I mentioned first responders, but because, now if you look at community stakeholder, because they don't like the term community, examples would be the population to be recruited, trial participants, people living in the area where research is conducted, people living with the condition, which is obviously not relevant, and then it goes on. And a lot of the other examples here are similar to, to the broader context of stakeholders. But I think you get an idea of, of the broadness.

And community engagement isn't a yes/no for any individual trial because ultimately it is going to be up to the IRBs and funders, right, to decide if the study is going to go forward.

DR. GUTMANN: But it is a matter of education--

DR. MICHAEL: It is.

DR. GUTMANN: Of getting the—

DR. WAGNER: Awareness

DR. GUTMANN: Of their awareness, but also the government's awareness of what the concerns are and the support is.

DR. MICHAEL: I think we can draw from this language if we choose to. Obviously it is now published, it has been validated now and a little bit outside of the HIV prevention field as well, but I think the critical point is to emphasize that this is a entire lifecycle process, that this is not a step that one does just before one executes the research.

DR. GUTMANN: Christine.

DR. GRADY: I was going to suggest, I like the stakeholder language, but we should include the sort of local and state public health communities in the stakeholders.

And then the other thing, based on what Nelson just said, I think maybe it belongs earlier in the framework, community engagement.

DR. GUTMANN: Since the framework is a set of necessary conditions, I don't think we should worry too much about it, but it maybe we can look at where it most--

DR. GRADY: Okay.

DR. GUTMANN: Logically flows, but we definitely want to include it and include it in this more detailed, robust way so it gives some, some sense of what we mean by it and I like the breakdown of recognizing what the different groups of stakeholders are because otherwise it is just so vague.

Okay, moving on to adequate provisions are made for soliciting the ascent of children and the permission of their parents or guardians as set forth in 46.48. Based on this criterion, the Commission--I'm just going to read and then stop and ask Lonnie to say something--reiterates the importance of informed consent, informed parental permission, and child assent.

And Lonnie, you thought, and I agree, that it is important to expand, especially given our discussion about how not using children or subjecting them to undue risks in the role that consent and assent plays here.

MRS. ALI: Yeah, I do and there was a lot of discussion yesterday about consent forms and how the traditional consent forms that are currently used may not be the best model for using it in these particular instances.

And I do have an issue with children being used, you know, as we have talked about, as a means to an end, so, therefore, when you talk about assent of children, what does that mean, that they clearly understand what is going on and the actual verbiage I think that is used in the consent form is very important.

And someone suggested, I don't remember who it was, that there was--that this consent be the same or the information be the same as presented to everyone. They did a little 30-minute presentation, I think of what they used, yeah, that I think is even better than just leaving it up to the individual to discuss with the parent and the child because it could be subjective and it could be coercive, so I think it is important that it happens.

DR. GUTMANN: So, so I just want to make sure in this report that we don't reduce the Government's decision as to whether to ask children to be subjects in above minimal risk research to what parents would allow their children to do because, and what reasonable parents, because parents have a latitude of discretion because they are the best guardians of their children. They have a vast latitude because we don't want the State to become the dictator of what parents do, so there is a broad latitude and parents--some parents are very risk averse with regard to their children and other parents have their children, as a recent article, running triathlons at great pain and so on to themselves and physical risk, and we allow a whole range. We draw the line at what parents can't do, but it is a very capacious line. That is very different.

This is where Lonnie's point is really important. I think we have to make sure that we're not saying in this report that the Government can subject children to the same risks that a parent would agree to subject children to, so this gets to Lonnie.

And there are many reasons for that because whenever the Government or an agent of the Government asks parents or children to do something, there will be some number of parents and children who step up to the plate no matter what they're being asked to do, especially if you just need a small number, and that would be an unethical way of proceeding. So I just want to make clear that the altruism of parents is fine and we can applaud it, but when the Government is asking children to do above minimal risk, we can't reduce that to altruism because it's just a different category.

MRS. ALI: Yeah. I think it comes down to that "prudent parent" and I think we had a little bit of a difference of what altruism is because I think Alan sort of alluded to the fact he was at a, at a church and children were going to, to go and do wonderful work for, for the hurricane victims. Well, for me that's, that's an acceptable--there is risk in doing that, of letting your children go out and doing that, but subjecting them to something with regards to a scientific study to me is something different, but I think that whole idea of "prudent parent" comes in and there may be limits that we need to, you know, like you said, you could have children doing all kinds of altruistic things, there may be ceiling that needs to be --you have to protect them in that regard.

DR. GUTMANN: Can I say where I think it is really important to make the distinction here—

MRS. ALI: Yeah.

DR. GUTMANN: You know, I think it is really important to distinguish between what we allow or applaud parents for asking their children to do altruistically and what we would say is justifiable for a government or society to try, because it is not, to try to get children to do and I think we have to--all of those examples of what parents will have their children do to me are beside the point. Um, that is, if parents wouldn't allow their children to do that then it would definitely be out, but the fact that they do, does not tell us that the Government could setup a program that tried to enlist children to do that.

Imagine the Government enlisting children, you know, the Government enlisting children to do all the risky things that good parents allow their children to do. That would not be the right thing to do. So I just want to make sure we don't go down that road. Dan.

DR. SULMASY: I think that at some point it would probably be valuable to have a little bit of discussion of what might be the motives for a parent to, um, you know, enroll a child in such a study and those included, you know, altruism, we're trying to raise a child with that kind of attitude.

It might include, as we heard, the first responders saying, they have a duty to protect their own family members and, therefore, want to see this sort of research done. It could be that parents think it comes down to the good of the individual, if the individual child is giving to others.

That being said, and that might be somewhere up the earlier part after principles, I think that, um, we are very concerned, as you are suggesting, about protecting children from parents who might be overzealous in that regard and there are two basic, um, strong barriers that we have here.

One, we talked about in terms of risk that we wouldn't allow any parent, um, to subject their child to and want to sort of say that.

And then the second one, um, is that the, um, consent of the parent is not, um, sufficient if the child does not also assent, if they are capable of it and that we ought, um, to build up a little bit more under this assent that we want, as Lonnie was suggesting, uniform procedures for this, um, that they should be developmentally appropriate, um, assent forms for children and that given the risks involved with this kind, um, of research that lack of assent essentially becomes a veto on whether this child can be enrolled. I think that is the way in which I would structure it.

DR. GUTMANN: Barbara.

DR. ATKINSON: I agree with that and particularly the assent part for the children.

But I really have a question about the wording here because the reg actually says assent of children and permission of their parents and I really had to struggle with whether they meant permission is an easier thing than consent, whether permission was something different.

We certainly say it is the same because we talk about informed consent, but I thought that maybe necessarily this wasn't an informed consent process. I think we should say it is, but I guess what I am saying is we may want to stress that difference if that's what--

DR. GUTMANN: I assumed it is, but rather than assume, I think we should assert that it must be. It must be informed consent. Nita.

DR. FARAHANY: I agree that it is important for us to include thresholds and say there are thresholds that parents cannot consent to certain types of risks for children, that the Government cannot ask certain types of risks.

I just want us to make sure that when we include that language, we are crystal clear about why and it's particular to children because children are unable to make the decision for themselves. And so not that we generally think it is impermissible to offer certain types of, or ask certain types of things of individuals, but just of children because they are unable to give fully informed consent or assent.

DR. GUTMANN: I think that--I very much agree with Nita's--there are many formulations of this, but I agree that Nita's formulation we should include as well, which is that an extremely important reason, ethical reason, why there are limits on what we allow government to ask children to undergo by way of risks that are not, um, for their own--directly for their own good is that children are not yet in the position of giving fully informed consent.

And I would add to that the Government is a different, um, entity over children than parents are and we set different limits for parents than we set for our Government and much more capacious for parents than for Government. They are not unlimited, but they are much broader because parents are, you know, for all the reasons which I have written about, and other people have too, we do not want to be setting up, um, um, a State which sees itself as the primary guardians of children.

DR. ALLEN: I would just like to say that this last bit of conversation with Barbara, Nita, and Dan helps me a lot because I was very worried yesterday that we didn't have on the table a thick enough set of reasons for thinking that we should, um, as parents and a community enroll children in this sort of research, but I feel like the conversation today about thresholds as an important thing, combined with Nita's concern about, about special vulnerability really does answer the kinds of questions I was raising yesterday, so I appreciate that.

DR. GUTMANN: Could we go back in this, at the end, to reiterate in this section, because I think it is relevant to this section, that among the reasons why we would recommend

considering these sets of conditions for allowing children to engage in research is that there is no other way that children, as a class, can be protected and, therefore, it isn't quite the same. It is a collective action problem within the group of children themselves to be protected, which is not-- is a subset of pure altruism, so it is in some sense altruistic to volunteer for something that you could be a free-rider on, but in another sense, it is a way of producing the very good that you may benefit from.

Now, we are not asking children, as Nita importantly said, we are not resting the justification here on the ascent of children, but it is among--if you are asking about the motives for a parent, one of the motivations for a parent is if my child is not being subjected to too much risk, if there is full compensation in place, and given that I know that if this research doesn't go forward, neither my child nor any other child will be protected, it seems like a reasonable thing to do. I think we should be specific about that. Christine.

DR. GRADY: Just a minor detail maybe. It seems to me that the, you know, all of the conditions we've setup are the process by which we decide, or somebody decides, the Government decides, what is acceptable to offer to parents and so before we even think about what the parents' motivations or willingness are, it is a decision about what is acceptable risk in light of the circumstances with problem of vital importance and all those other things that we have talked about, so that is the package that needs to be sort of thought through before we offer parents the opportunity to enroll.

The second thing that I would say is that I think that the issue requiring ascent in every research study is actually already part of the regs, so we should, you know, highlight that, but it is true for all kinds of research, except for the smaller category of research that is a possible direct benefit to the child and in the regulatory framework there is an option in that case, and that case only, for parents to override their child's ascent.

DR. GUTMANN: Right. Good. Anything else? I know I am at the end of the--

DR. WAGNER: We have given ourselves some homework at the very end of the document to write--to provide illustrations and I think we still intend to do that.

DR. GUTMANN: Right. I think we also, um, Lisa and our terrific staff will help us in getting the best, the best ones, um. I uh--

DR. FARAHANY: Can I just—

DR. GUTMANN: Sure.

DR. FARAHANY: Going back, this is just a small point, but one that I had a question mark on yesterday, so this is under 2, Scientific Validity and Ethical Research Design in the Testing of Adults.

DR. GUTMANN: Go slow because I have to find it first.

DR. FARAHANY: So it is 2--it is number one, I'm sorry it is number two under two, Sound Ethical Principles.

DR. GUTMANN: Right.

DR. FARAHANY: Number two, Scientific Validity and Ethical Research Design and then the second bullet is tested in adults.

DR. WAGNER: Testing in adults. Okay.

DR. FARAHANY: Yep.

DR. GUTMANN: Got it.

DR. FARAHANY: And I just wanted us to specify this more, um, and so here we say where an adult formulation is appropriate, the intervention has been thoroughly and safely tested in adult populations, with regard to the same issues that we studied in children and as I have been thinking about the anthrax example here, one problem with the number of countermeasures, in particularly anthrax, is we are able to test it for safety, we are able to test it for immunogenicity, but we are not able to test it for efficacy, um, and so I just want to be clear that when we say tested in adults that is sufficient, right? I mean, so whatever testing we can do, we have done in adults, recognizing that we will not have been able to test for every parameter that we might wish to know before testing in children.

DR. GUTMANN: And I think we should explain why in all of these because that will give the best possible available knowledge to using the right dosages in the trial with children, so all of this may be obvious to us who have been in this, you know, for--but I think when we write down, we should write for an audience that includes people who we--to whom we owe reasons for these.

DR. FARAHANY: Right, and I just mean, you know, so as we start to think about examples in that one, we need to be that specific to say, you know, in certain types of circumstances, efficacy cannot be tested because it cannot be ethically tested in humans, you know, by giving--

DR. WAGNER: In adults.

DR. FARAHANY: In adults to give efficacy studies can't be taken out in anyone.

DR. GUTMANN: But safety and immunogenicity can be.

DR. FARAHANY: Exactly, and so the nature of the type of studies that we are doing are ones that we have fully tested in adults, recognizing not every type of testing can first happen in adults.

DR. GUTMANN: Good. Okay. I think we are ready to wrap up. And I want to thank-- Barbara, we are not--Barbara, we are almost ready.

DR. ATKINSON: Almost ready.

DR. GUTMANN: That's okay. Barbara.

DR. ATKINSON: Just one quick comment, in the clippings we just got, the FDA panel just approved a monoclonal antibody for use in anthrax. It would be used either instead or together with an antibiotic and I was thinking about that and, um, it would have to be through the same kind of an exact same procedure. It may be easier than a vaccine, but it is just interesting to think this would cover that opportunity, as well as a vaccine opportunity.

DR. GUTMANN: Right.

So I want to thank again all the presenters, thank all the members of the public who have given as feedback, thank, of course, my colleagues on the Commission for their ongoing hard and good work on this, thank Dan having for us here and thank the angles for looking down on us and asking them for continued in spirit guidance for our ongoing deliberations. We will continue this work after the holiday--we will continue in moving the draft forward on the basis of these deliberations, but we will have another meeting of the Commission in January where we hope to be in a position of actually having a set of draft recommendations to deliberate about. I will wish everybody safe travels, but I also want to ask Jim, who began this proceeding, if he has something to add--

DR. WAGNER: You have closed it beautifully. Amen to all of your thanks and thank you for your leadership.

DR. GUTMANN: Well, thank you. Thanks everybody. Thank you all.
(Clapping)